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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,495	11/13/2000	Bruce Joseph Roser	P65952US0	9084

136 7590 01/28/2003

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EXAMINER

HENRY, MICHAEL C

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 01/28/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/623,495

Applicant(s)

ROSER ET AL.

Examiner

Michael C. Henry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2002 and 10/25/02.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The following office action is a responsive to the Amendment filed, 09/04/02 and the supplemental Amendment filed, 10/25/02.

The amendment filed 09/04/02 and the supplemental Amendment filed, 10/25/02 affect the application, 09/623,495 as follows:

1. Claims 1, 7 and 15 have been amended. Claims 16-20 have been added. This leaves Claims 1-20.
2. Applicant responds to the rejection under 35 USC 102(b) by amending claims 1, 7, and 15. Applicant responds to the 112 2nd rejection by amending Claims 3 and 7.

The responsive to applicants' arguments is contained herein below.

Claim Objections

Claim 19 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 7.

When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-10, 15, 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Foster et al. (US 6,258,341 B1).

In claim 1, applicants' claim "a method for producing a dried product which is an amorphous sugar glass without crystals therein which comprises (a) forming an aqueous system which is a solution of (i) one or more monosaccharide sugar alcohol which would normally form sugar crystals on drying; (ii) a compound which is normally subject to deactivation on drying, or a mixture of such compounds; and (iii) at least one additive which is a glass-former or a formulation-facilitator, the total amount of the additive being sufficient to cause the monosaccharide sugar alcohol to form a glass on drying; wherein the additive itself does not crystallize during the drying step (b); (b) drying the aqueous system at a temperature above its freezing point; and (c) solidifying the component (i), (ii) and (iii) as an amorphous glass without crystals therein, whereby the amorphous glass stabilizes the compound or mixture of compounds therein and prevent damage thereto during drying." Foster et al. disclose a method for producing a dried product which is an amorphous sugar glass without crystals therein which comprises (a) forming an aqueous system which is a solution of (i) one monosaccharide sugar alcohol (mannitol) which would normally form sugar crystals on drying; (ii) a compound which is normally subject to deactivation on drying (Human zinc insulin); and (iii) at least one additive (sodium citrate) which is a glass-former or a formulation-facilitator, the total amount of the additive being sufficient to cause the monosaccharide sugar alcohol to form a glass on drying; wherein the additive itself does not crystallize during the drying step (b); (b) drying the aqueous system at a temperature above its freezing point; and (c) solidifying the component (i), (ii) and (iii) as an amorphous glass without crystals therein, whereby the amorphous glass stabilizes the

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compound therein and prevent damage thereto during drying (example 3, col. 23; see also, table 1, col. 14, lines 49-65; see also example 1, col. 18 and example 2, col. 20). Claims 2-10, 15, 19 and 20 are also rejected because, the limitations and/or dependability encompassed by these claims are also anticipated by Foster et al. (example 3, col. 23; see also, table 1, col. 14, lines 49-65; see also example 1, col. 18 and example 2, col. 20).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-14, 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foster et al. (US Patent No. 6,258,341 B1).

In claim 1, applicants' claim "a method for producing a dried product which is an amorphous sugar glass without crystals therein which comprises (a) forming an aqueous system which is a solution of (i) one or more monosaccharide sugar alcohol which would normally form sugar crystals on drying; (ii) a compound which is normally subject to deactivation on drying, or a mixture of such compounds; and (iii) at least one additive which is a glass-former or a formulation-facilitator, the total amount of the additive being sufficient to cause the monosaccharide sugar alcohol to form a glass on drying; wherein the additive itself does not crystallize during the drying step (b); (b) drying the aqueous system at a temperature above its freezing point; and (c) solidifying the component (i), (ii) and (iii) as an amorphous glass without crystals therein, whereby the amorphous glass stabilizes the compound or mixture of compounds

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therein and prevent damage thereto during drying.” In claim 7, applicants claim a dried product which is an amorphous glass without crystals therein, comprising one or more monosaccharide sugar alcohol and at least one additive which is a glass-former or a glass-formation-facilitator and a compound which is subject to deactivation on drying, or a mixture of such compounds, in a weight ratio of sugar alcohol plus additive to compound of at least 0.5:1, the product having been dried from aqueous solution at a temperature above its freezing point. Claims 11-14, 16 and 17, applicants claim a method or product pertaining to specific additives or monosaccharide alcohols.

Foster et al. disclose a product or method for producing a dried product which is an amorphous sugar glass without crystals therein which comprises (a) forming an aqueous system which is a solution of (i) one monosaccharide sugar alcohol (mannitol) which would normally form sugar crystals on drying; (ii) a compound which is normally subject to deactivation on drying (Human zinc insulin); and (iii) at least one additive (sodium citrate) which is a glass-former or a formulation-facilitator, the total amount of the additive being sufficient to cause the monosaccharide sugar alcohol to form a glass on drying; wherein the additive itself does not crystallize during the drying step (b); (b) drying the aqueous system at a temperature above its freezing point; and (c) solidifying the component (i), (ii) and (iii) as an amorphous glass without crystals therein, whereby the amorphous glass stabilizes the compound therein and prevent damage thereto during drying (example 3, col. 23; see also, table 1, col. 14, lines 49-65; see also example 1, col. 18 and example 2, col. 20). In addition, Foster et al. disclose a method and product of elcatonin powder prepared from elcatonin and glass formers and additives (example 18, col. 43).

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The difference between applicants claimed method or product and the method or product that is exemplified by Foster et al. is that, Foster et al. do not disclose the identical glass formers or additives like those claimed by the applicants'. However, Foster et al. suggest that additives used by the applicants including, peptides, proteins, and salts like calcium lactate, sodium tetraborate can be used (col. 12, lines 25-37), (col. 13, lines 13-20), (col. 12, line 65 to col. 13, line 12). Foster et al. also suggest that monosaccharide sugar alcohols other than mannitol (like xylitol and sorbitol) can be used (col. 11, lines 24-36).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to use the method of drying of Foster et al. to prepare amorphous glass of products of compounds using different monosaccharide sugar alcohols and additives.

One having ordinary skill in the art would have been motivated, in view of Foster et al., to prepare amorphous glass of products of compounds using different monosaccharide sugar alcohols and additives, depending on cost, availability and/or convenience of use. The preparations of different amorphous glass compositions are well known in the art.

In claim 18, applicants claim a method or product according to claim 1 wherein the amorphous glass is formed from a formulation having essentially a composition selected from: (12). Mannitol 50%, and dextran 50%.

Foster et al. disclose a method and product of claim 1 consisting of mannitol and other additives (example 3, col. 23; see also, table 1, col. 14, lines 49-65; see also example 1, col. 18 and example 2, col. 20).

The difference between applicants claimed method or product and the method or product that is exemplified by Foster et al. is that, Foster et al. do not disclose the use of dextran in

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combination with mannitol. However, Foster et al. suggest that dextran is a glass former (see table 1, col. 14, lines 49-65). In addition, Foster et al. use more than one additive in his method.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to use the method of drying of Foster et al. to prepare amorphous glass of products of compounds using different monosaccharide sugar alcohols and/or additives in different percent combinations.

One having ordinary skill in the art would have been motivated, in view of Foster et al., to prepare amorphous glass of products of compounds using different monosaccharide sugar alcohols and/or additives in different percent combinations, depending on cost, availability and/or convenience of use. The preparations of different amorphous glass compositions are well known in the art.

Response to Amendment

Applicant's arguments filed September 20, 2002 have been fully considered but they are not persuasive.

The applicant argues that the present invention provides methods to form the highly desirable, adaptable non-critical glasses of sugar derivatives such as mannitol. He further states that the present invention surpasses the prior art and extends the field of non-critical adaptable glasses from single natural glass formers such as sucrose, raffinose or trehalose to complex mixtures of non-natural glass formers such as readily crystallizable sugars alcohols like mannitol. However, Foster et al. also use the readily crystallizable sugars alcohols, mannitol. Furthermore, the applicant argues that the adaptable glasses of the present invention are therefore able to contain and stabilize a wide range of types of actives, both glass formers and non-glass

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formers and in a very wide range of concentrations, rather than having the severe concentration constraints as seen when the active itself is required to facilitate glass formation as in the prior art, such as in Foster et al. and U.S. Pat. No. 5,589,167. However, Foster et al. teach that their glasses are able to contain and stabilize a wide range of types of actives, both glass formers and non-glass formers (e.g. nonmacromolecule pharmaceuticals and macroparmaceuticals like estrogen, progesterone, dexamethasone, calcitonin, erythropoietin, cyclooxygenase (see col. 8 lines 39 to col. 9, line 34)) and in a very wide range of concentrations. More specifically, Foster et al. teach that in preparing the compositions of their invention, the pharmacologically active material will be present in amount that range between about 0.05%w for a drug that is not very active material to about 99%w for a drug that is not very active and is a glass former itself (col. 14, lines 66-67 to col. 15, lines 1-3). Foster et al. also teach the use of preferred %w ranges of the active materials(col. 15, lines 3-5). Furthermore, Foster et al. do not specifically or generally teach any severe concentration constraints when the active material itself facilitates glass formation. And, arguments by applicants pertaining to the lack of concentration constraints in their method is not contained in their claims. In addition, no comparative test was done to support said arguments. Moreover, the applicants' invention, as claimed, is anticipated and is obvious over Foster et al. as indicated in the above rejections.

The Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 703 308-7307. The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703 308-4624. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

MCH

January 22, 2003


SAMUEL BARTS
PRIMARY EXAMINER
GROUP 1600